

Deanie Morello - Simulations  
Data management - sent to Hans  
Mean values

NNIL -  
e-mail to Roelud

**Nelson, Bettie L**  
**From:** Nelson, Bettie L  
**Sent:** Monday, October 15, 2001 3:33 PM  
**To:** Roethig, Hans  
**Subject:** REPRESENTATIVE SAMPLE

Hans,

The Data Analysis Team has had considerable discussion regarding the manner in which sampling for the Total Exposure Study (TES) should be conducted. We have expressed our concerns to the CRO. At the heart of the issue is whether the sample selected should be representative of the population of smokers in the United States. Because of the importance of this study, the manner in which the sample is selected is crucial and will definitely affect the integrity of the resulting data.

We asked for an opinion from the CRO on this matter but they had difficulty obtaining someone with sampling experience. We have taken the liberty of discussing this problem informally with an expert in the sampling field. He agrees that recruiting subjects into the study as the CRO has done before produces a "convenience sample", which will not necessarily be representative of the population. However, the current study recruitment plan will yield a sample that contains representation from the demographic sub-groups of interest. Additionally, more solid inferences for demographic sub-groups may be made if we have equal cell counts, instead of recruiting so that the marginals represent the population distributions. He further indicated that if he were asked to professionally critique the study, that he would have some issues with the sample selection process as it is currently going forth.

The Data Analysis team is requesting feedback from you on whether there is a need to select the sample for the main TES in such a way that it is a representative sample of U.S. smokers. If so, that would mean that subjects must be recruited through a random digit dialing process, and randomly selected after this recruitment. This would be done at some increased cost, and the CRO will need to sub-contract this recruitment to a large survey research facility. If representativeness is not required then the study may be conducted as is currently planned, and results will be from a sample with representation from the demographic sub-groups of interest. Regardless, we will recruit so that there are equal numbers in the cells.

Either way that we go, a survey sampling expert should be retained as a consultant, so that their written input on the sampling plan can then be used as a reference.

Please let me know when we can discuss.

With best regards,

*Bettie*

PM3005195882